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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,610	07/11/2003	Venkataramana Vijay	VII-003 A	2900
36822	7590	09/03/2004	EXAMINER	
GORDON & JACOBSON, P.C. 65 WOODS END ROAD STAMFORD, CT 06905			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER

3738

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/617,610	Applicant(s) VIJAY, VENKATARAMANA	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/23/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "said ring" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 and 13-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Loch et al. (US 6,174,332 B1). Referring to claims 1, 6, 13, 18, and 20, Loch discloses a mitral annuloplasty device (fig.1, 2) comprising a ring shaped structural component (10) having a relatively shallow curved anterior portion (anterior portion being top 1/3 of ring shown in fig.1 and 2; a portion of segment 12; will inherently be shallower when implanted due to the shape of

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the valve, also, disclosed is a D-shape, col.2, lines 48-50, 59-61) and a relatively steeper curved C-shaped posterior portion (posterior portion being the bottom portion of ring in fig.1 and 2; posterior portion includes segment 18 and *portions* of segment 12; will inherently be steeper when implanted due to the shape of the valve, col.2, lines 48-50, 59-61) including a central portion (18) and first and second lateral portions (portions of segment 12 adjacent segment 18), wherein the posterior portion includes demarcations (14, 16) between the central portion (18) and both the lateral portions (portions of 12), facilitating removal of the central portion (18) from between the lateral portions (side portions of 12), (col.3, lines 58-67). Loch discloses lateral portions substantially transverse to the central portion (fig.1, 2).

Referring to claims 2, 3, 5, 14, 15, and 17, Loch discloses demarcations (14, 16) that are structural (may be sutures, col.4, lines 1-2) and further has visual indicia (14 and 16 are also visual, and in addition to these, stitches 34 serve as indicia, fig.1, 2, col.4, lines 26-28) coincident with the structural demarcations. Loch discloses the lateral portions to have markings (34, 14, 16).

Referring to claims 4, and 16, Loch discloses the structural component provided with a softer outer layer (36), wherein visual indicia (14, 16, 34) are present on the outer layer (36; fig.1, 2, 3b).

Referring to claims 7, 8, 19, and 21, Loch discloses lateral portions (side portions of 12), which are stiffer than the central portion (18) and also having a more round cross-section (lateral portions will be stiffer and have a different cross section due to the presence of core 50, which is not present in the central portion, see fig.2, 3a, 3b).

Referring to claims 9, 10, 11, 22, 23, and 24, Loch discloses a means (34) for identifying suture locations, the means being visual indicia having a color and shape (stitches 34 have a color and a shape and are used for orientation indication reasons, col.4, lines 25-30).

Claims 13-19 and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Colvin et al. (US 6,602,289 B1). Referring to claims 13 and 18, Colvin discloses a mitral annuloplasty device (col.5, lines 10-15) comprising a C-shaped structural component (fig.1) having a central portion (center of partial ring in fig.1) and first and second lateral portions (end portions of ring in fig.1), wherein the component includes demarcations (apertures 32 or colored markings, col.6, lines 55-65) between the central portion and both the lateral portions (fig.1), facilitating removal of the central portion from between the lateral portions (the central portion is *capable* of being removed). Colvin discloses lateral portions substantially transverse to the central portion (fig.1).

Referring to claims 14, 15, and 17, Colvin discloses demarcations (32) that are structural (apertures, fig.1; col.4, lines 5-11) and further has visual indicia (col.6, lines 55-65) coincident with the structural demarcations. Colvin discloses the lateral portions to have markings (32, fig.1).

Referring to claim 16, Colvin discloses the structural component provided with a softer outer layer (100; cloth covering, col.6, lines 34-45), wherein visual indicia (apertures or colored indicia, col.6, lines 55-65) are present on the outer layer.

Referring to claims 19 and 21, Colvin discloses lateral portions (ends), which are stiffer (due to curled end of element 16, seen in 3) than the central portion (middle) and also having a more round cross-section.

Referring to claims 22, 23, 24, and 25, Colvin discloses a means for identifying suture locations (apertures 32), the means being visual indicia having a color and shape and spaced apart differently (col.6, lines 55-65).

Claims 1-7, 9-20, and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Healy et al. (US 6,074,419). Referring to claims 1, 6, 13, 18, and 20, Healy discloses a mitral annuloplasty device (fig.7) comprising a ring shaped structural component having a relatively shallow curved anterior portion (side labeled 27mm) and a relatively steeper curved C-shaped posterior portion (side labeled ventricular side) including a central portion and first and second lateral portions, wherein the posterior portion includes demarcations (col.4, lines 31-42) between the central portion and both the lateral portions, facilitating removal of the central portion from between the lateral portions (col.1, lines 60-65; col.2, lines 38-48). Healy discloses lateral portions substantially transverse to the central portion (fig.7).

Referring to claims 2, 3, 5, 14, 15, and 17, Healy discloses demarcations that are structural and further has visual indicia coincident with the structural demarcations (laser markings are structural, col.3, lines 33-39; col.4, lines 31-42; visual indicia being dye, color, etc.). Healy discloses the lateral portions to have markings.

Referring to claims 4, and 16, Healy discloses the structural component (fig.7) provided with a softer outer layer, wherein visual indicia are present on the outer layer (col.4, lines 31-42; col.5, lines 1-5).

Referring to claims 7 and 19, Healy discloses lateral portions, which are stiffer than the central portion and also having a more round cross-section (col.4, lines 35-38).

Referring to claims 9, 10, 11, 12, 22, 23, 24, and 25, Healy discloses a means for identifying suture locations, the means being visual indicia having a color and shape and spaced apart differently (col.3, lines 54-63; col.4, lines 31-42; col.5, lines 7-15, 20-25).

Referring to claims 26-27, Healy discloses a method for mitral valve annuloplasty comprising providing an annuloplasty device (fig.7) having a central posterior portion (center of side labeled ventricle side) and first and second lateral posterior portions (portions connecting the ventricle side to the 27mm side), coupling lateral posterior portions of an annulus of the mitral valve to the first and second lateral posterior portions of the annuloplasty device (implantation, col.5, lines 5-15), and removing the central posterior portion of the annuloplasty device (modification indicators and cut line indicators disclosed, inherently allow removal, col.4, lines 31-39; col.1, lines 61-65; col.2, lines 38-48) while maintaining the lateral posterior portions coupled to the annulus. Healy discloses an annuloplasty device having a varied thickness/stiffness (col.4, lines 35-37).

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by St.Jude Medical (SJM Tailor Annuloplasty Ring, 2000, cited by applicant in IDS). St. Jude Medical discloses a method for mitral valve annuloplasty (pg.3) comprising providing an annuloplasty device (full

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ring or C-ring) having a central posterior portion (portion shown cut out on pg.2) and first and second lateral posterior portions (portions to the side of the cut on pg.2), coupling lateral posterior portions of an annulus of the mitral valve to the first and second lateral posterior portions of the annuloplasty device (implantation disclosed on pg.3), and removing the central posterior portion of the annuloplasty device (right fig. on pg.3 shows "The surgeon can easily cut the ring...when desired", therefore, it may be cut after implantation) while maintaining the lateral posterior portions coupled to the annulus.

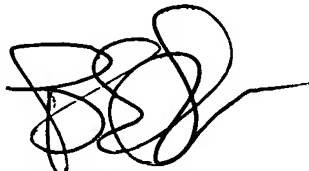
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Cheryl Miller


BRUCE SNOW
PRIMARY EXAMINER